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| 10/681,722      | 10/08/2003  | Peter B. Lockhart    | 163P015             | 6702             |

7590 08/22/2007  
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| EXAMINER |
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TALMAN, JAMES R

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| ART UNIT | PAPER NUMBER |
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3737

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08/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/681,722

Applicant(s)

LOCKHART ET AL.

Examiner

James R. Talman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 12, 16, 18, 20, 30, 34, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Altshuler (US 5873875). Altshuler discloses a system for the treatment of biological tissue, including teeth (col 1, lines 8-25), and further discloses that the status of a tissue can be represented (col 2, lines 42-53). Pulsed lasers or light sources are used to illuminate the tissue (col 4, line 34) and embodiments are disclosed using either 2 or 3 light sources (col 4, line 34). Light used is within either the visible, near IR, or UV spectral ranges (col 5, lines 30-32). The detector may be an acoustic detector placed near the laser-tissue interaction field (col 4, lines 64-66), which therefore detects shockwaves induced by the laser light (col 6, lines 1-12). There may be anywhere from 1 to 9 detectors used in the system to detect the status of the tissue (col 5, lines 1-5), such as degree of necrosis (col 6, line 12).

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-7, 9-11, 13, 21-25, 27-29, 31, 35-40, 42-44, 46 rejected under 35

U.S.C. 103(a) as being unpatentable over Altshuler in view of Schmitt, et al (US 5040539). Altshuler, as discussed above, discloses the invention as claimed, however fails to disclose specific frequencies used and their absorption coefficients. Schmitt discloses a pulse oximetry system for diagnosis of dental pulp pathology and further discloses the use of multiple LEDs with different frequencies used to determine the health of a tooth, specifically by providing the oxygen saturation of hemoglobin in the pulp (col 2, lines 25-35). Schmitt discloses the use of red, infrared (IR), and green LEDs (fig. 9). Red light has a high absorption coefficient for oxygenated blood and infrared light has a high absorption coefficient for deoxygenated blood. Schmitt discloses that enamel and dentin have a weak dependence on wavelength at the visible and near infrared spectral region and therefore both infrared and red light frequencies would have a high contrast in absorption as compared to enamel and dentin (col 7, lines 21-45). The LEDs are pulsed in sequence and therefore modulated by the pulse drivers (col 10, line 7) and may also be activated to allow nearly simultaneous measurement of intensity at the different wavelengths (col 10, lines 9-11). A microprocessor computes the oxygenation level (col 10, lines 32-33) and allows for display of information regarding the status of the tooth (col 10, line 65). Schmitt additionally discloses the use of white light (fig. 7), which is a broadband light source which is at a frequency that does not have a specific absorption difference without the use of filters (col 4, lines 4-19).

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Although Altshuler discloses the use of modulated light, he fails to explicitly disclose the best frequencies for use in the system. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Altshuler in light of the teachings Schmitt to use frequencies with absorption coefficients which sufficiently allow for discrimination between blood and non-blood tissue or oxygenated and non-oxygenated tissue for examination of the health of a biological tissue, such as a tooth.

5. Claims 8, 26, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altshuler in view of Schmitt as applied to claims 3, 21, and 36 above, and further in view of Yamashita, et al (US 2001/0018554). Although both Altshuler and Schmitt disclose the use of modulated light, they fail to explicitly disclose the modulation frequency used. Yamashita, in the same field of endeavor, discloses an optical measurement system for the living body. Yamashita additionally discloses that the light sources are modulated with mutually different modulation frequencies in the range of 100Hz to 10MHz (paragraph 117). This modulation allows the operation unit to compute the oxyhemoglobin and deoxyhemoglobin concentration changes (paragraph 122). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Altshuler in view of Schmitt in light of the teachings in the reference by Yamashita to use modulation frequencies between 100Hz and 10MHz to allow computation of oxyhemoglobin and deoxyhemoglobin concentration changes from multiple light sources, as is well known in the art.

6. Claims 14, 32, 47 rejected under 35 U.S.C. 103(a) as being unpatentable over Altshuler in view of Anderson, et al (US 6436127). Altshuler, as discussed above.

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discloses the invention as claimed, however fails to explicitly disclose the use of polarized light. Anderson discloses a system for the detection and treatment of tissue and further discloses that the use of polarized light is preferred for use in diagnostics, as the measurement of diffuse reflectance includes information about reflectance from within the tissue, such as from erythema (col 7, lines 60-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Altshuler in light of the teachings of Anderson to use polarized light in order to provide improved detection of erythema below the tissue surface, such as the inside of a tooth.

7. Claims 15, 33, 48 rejected under 35 U.S.C. 103(a) as being unpatentable over Altshuler in view of Balbierz, et al (US 2002/0026127). Altshuler, as discussed above, discloses the invention as claimed, however fails to disclose the use of a comparison database to healthy tissue. Balbierz discloses a system for the detection and treatment of tissue using optical means and further discloses analyzing tissue types using a database of spectral profiles with pattern recognition techniques to differentiate between abnormal and healthy tissue (paragraphs 65-67). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Altshuler in light of the disclosure of Balbierz to include a database of healthy tissue profiles to allow for automatic detection and classification of tissue which improves accuracy, speed, and reliability of the tissue detection.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altshuler in view of Jenkins (US 5109859). Altshuler, as discussed above, discloses the

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invention as claimed, including both a light source and an ultrasonic detector, however fails to explicitly disclose the use of a probe surrounded by the detector in a single unit. Jenkins discloses a probe that includes an ultrasonic transducer surrounding a fiberoptic light source (figure 4b). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Altshuler in light of the teachings in the reference by Jenkins to include both the light source and the detector in a single probe to reduce the size of the system and allow for improved accuracy, as the detector will be lined up with the light source without a need for calibration, as the two will be mechanically linked.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altshuler in view of Belleville, et al (US 5202939). Altshuler, as discussed above, discloses the invention as claimed, however fails to explicitly disclose the use of a Fabry-Perot ultrasound sensor. Belleville discloses an optical system for the measurement of a physical parameter and further discloses the use of a Fabry-Perot sensor. A variety of ultrasound transducers or sensors or detectors are known in the imaging art and it is well known that such a sensor would serve the purpose as disclosed by Altshuler. The substitution of one sensor for another is not in and of itself a patentable distinction.

### ***Response to Arguments***

3. Applicant's arguments, with regards to claims 1-48, filed 1/5/2007, have been fully considered but they are not persuasive.

4. On page 3 of the Applicant's Response, applicants argue that Altshuler is drawn to a method for treating tooth disease whereas the instant application is drawn to a method for diagnosing tooth disease and therefore Altshuler does not anticipate the instant application.

5. The examiner respectfully disagrees with Applicant's arguments because Altshuler discloses that the status of a tissue can be represented (col 2, lines 42-53), as stated in the original Detailed Action of 8/9/2006. It is the examiner's position that determining the status of a tissue is equivalent to diagnosing said tissue.

6. On page 3 of the Applicant's Response, applicants argue that Altshuler is drawn to a method for detecting necrosis, and therefore cannot be used as a method for detecting erythema.

7. The examiner respectfully disagrees with Applicant's arguments because, even if the sole goal of the method of Altshuler is to induce necrosis, as posited by the applicant but as disagreed with by the examiner, the method of Altshuler is capable of detecting intermediate states of the tissue prior to necrosis and therefore is capable of detecting different degrees of vascularization, e.g. erythema.

8. On page 4 of the Applicant's Response, applicants argue that modifying the lasers of Altshuler to deliver red light would render the system useless for surgical procedures, as red light is incapable of causing the necessary destruction of tissue. Applicant argues therefore that the use of red light would destroy the primary invention of Altshuler, making the combination improper for an obviousness rejection.



9. The examiner respectfully disagrees with Applicant's arguments because Altshuler discloses that the status of a tissue can be represented (col 2, lines 42-53), as stated in the original Detailed Action of 8/9/2006. Therefore, it is not the sole goal of Altshuler to destroy tissue. Furthermore, it is the examiner's position that at sufficient intensity levels red light could indeed be effective at destroying tissue. Furthermore, the use of red light in the system of Altshuler would not necessitate any significant structural modification but would only require obvious design changes such as using fibers and detectors sensitive to the appropriate wavelength.
10. Therefore, in view of the above reasons, the examiner maintains rejections.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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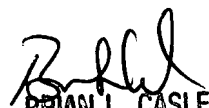
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James R. Talman whose telephone number is 571-270-3029. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner  
Art Unit 3737

Jrt

  
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